RAW PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

1. List the main pathogen of concern for raw ground beef products.
2. Select, from a list, those raw products subject to sampling under 05B02.
3. State where to find FSIS sampling instructions.
4. Explain the use of FSIS Form 10,210-3.
5. List, in order, the steps of sampling.
6. Describe how to determine which product to sample.
7. State how sample results are received.
8. State when to mail samples.
9. List the actions associated with positive microbial results.
10. List the requirements for transportation of product which has tested positive or presumptive positive for a pathogen.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused food borne illness. FSIS works with other governmental agencies, academia, industry, and consumer groups to set policy and establish guidelines and performance standards to reduce or eliminate pathogens from meat and poultry products. Each package of federally inspected product that is recalled bears the mark of inspection, which the public has come to trust as a sign that the product is safe. FSIS intends to maintain that public trust. To that purpose, FSIS samples products to detect pathogens in raw product processing establishments.

One way FSIS protects public health is by keeping pace with changes, such as emerging pathogens, new products and processes, and new laboratory analyses methods. You are responsible for properly selecting products and using appropriate sample collection techniques to ensure the integrity of samples received by the laboratories.

FSIS focuses its efforts based on ***risk***. Currently, FSIS is concerned with *E. coli* O157:H7 in raw beef because of its public health significance. Non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated. Intact raw beef products contaminated with *E. coli* O157:H7 and that are intended to be processed into non-intact products are also adulterated.

All establishments producing non-intact raw beef products, including ground beef products, raw ground beef components, or raw beef patty components are subject to sampling per FSIS Directive 10,010.1, Revision 1 “Microbiological

Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components." However, at the present time, the primary focus of this sampling program will remain on raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix (per FSIS standard of identity in 319.15(a), (b) and (c). When FSIS samples test positive for *E. coli* O157:H7, you may sample non-intact or intact beef intended for use in ground beef products.

FSIS is continuously improving its sampling protocol and techniques, updating sampling programs, and developing more rapid means of reporting results. FSIS directives and notices contain policy details specific to sampling projects and programs (see Attachment 2). Policy changes rapidly and amendments and new issuances are developed to keep you informed. You must use the updated resources ***each*** time you take a sample. You should read issuances when they are published, such as FSIS Directive 10,010.1, Revision 1 (issued in May 2004).

FSIS Directive 10,010.1 contains key concepts regarding products that test positive for *E. coli* O157:H7. These include

- Expanded policy to include components (intact and non-intact)
- No exemption from sampling
- May sample non-intact and intact ground beef components
- Verifying product disposition outside the plant
- Follow-up sampling after an FSIS positive sample
- FSIS verification at establishments producing components
- Plant-generated samples
- Instructional and disclaimer statements

Sampling is part of FSIS verification activities to ensure the protection of public health. HACCP programs integrate science-based controls into food production processes. These controls must be combined with some means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. FSIS microbiological sampling programs are designed to verify that HACCP programs are effective in controlling harmful microorganisms in meat and/or poultry products. Establishments may also include a microbiological sampling program into their HACCP system in order to verify that the system is performing as intended.

***Note**: The focus of the rest of this module is on the food safety aspects of sampling for verifying HACCP procedure code 03B for raw product.*

Currently for raw products, FSIS emphasizes analyses of raw ground beef products, raw ground beef components, and beef patty components. The sampling program is MT03/MT04 (subject to change) for the raw ground beef products.

The objective of this sampling program is to test for *E. coli* O157:H7, and, as a result, stimulate industry actions to reduce the presence of that pathogen in raw ground beef.

Definitions

Aseptic Techniques
An aseptic technique implies that you do not add any organisms to the sample when it is collected. It does **not** imply that the **sample** is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample ***or*** the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is ***intact***. Wash and sanitize your hands before collecting an intact sample. Good personal hygiene is **essential** anytime a sample is collected, whether it is intact or not.

Baseline
These are sampling programs to determine the industry-wide prevalence of an organism in/on a certain type of product. From these baseline studies, FSIS may establish performance standards.

Non-intact beef products
Non-intact beef products include ground beef, beef that has been injected with solutions, beef that has been mechanically tenderized by needling, cubing, Frenching, or pounding devices, and beef that has been reconstructed into formed entrees. Frenching is a method of preparing boneless chops by flattening with a cleaver.

Note: An **intact** *beef product is one in which nothing has penetrated into the muscle beyond the normal cut-up processes, such as primal cuts, subprimal cuts, steaks, roasts, boned out chucks, etc.*

Raw beef patty components
These components include all components listed for raw ground beef products, as well as partially defatted chopped beef (PDCB), finely textured PDCB, heart, and partially defatted beef fatty tissue (PDBFT). These products are subject to FSIS testing.

Raw ground beef products
Raw ground beef products covered under the *E. coli* O157:H7 sampling programs (MT03/MT04) include any raw (chopped or ground) beef or veal. Such products are ground beef, hamburger, veal patties, and beef patty mix (per §319.15(a), (b), and (c)) produced at and shipped from the establishment.

Raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix are included in FSIS sampling for *E. coli* O157:H7. Ground

or chopped products made from both beef and other meat or poultry products and beef sausage products are not subject to FSIS sampling for *E. coli* O157:H7. A raw ground beef product that contains any amount of beef product derived from advanced meat recovery (AMR) systems is considered a raw ground beef product. Raw product comprised only of beef from AMR systems is ***not*** considered a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component.

Raw ground beef components
These are intact or non-intact beef products intended for manufacturing into ground beef products identified in 319.15(a), (b), or (c). Such products include raw esophagus (weasand) meat, head meat, and cheek meat, beef manufacturing trimmings, boneless beef, beef from AMR systems, and lean finely textured beef (LFTB). These products are subject to FSIS testing.

Recall
A recall is a plant's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

Product that is adulterated and has left the establishment's control may be subject to a recall. The Recall Management Division (RMD) is notified immediately if product has left the establishment's control, and they coordinate any recall activities. The DO notifies the RMD (see FSIS Directive 8080.1, Rev. 4, Recall of Meat and Poultry Products). RMD is notified so a press release can be issued and effectiveness checks can be performed. The press release has the product name, lot number and the supplier. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the RMD of all factors in the situation. All recalls of meat and poultry products are voluntary.

Raw beef products produced on the shift represented by the positive sample would be subject to voluntary recall. If the raw beef product was used as an ingredient in other raw products, those secondary products would also be subject to recall. If the positive product was used as an ingredient in cooked products or other further processed products, the FSIS Recall Committee evaluates the situation and proceeds on a case-by-case basis.

Sample
A sample for raw products is a collection of product that represents a larger group (the sampled lot).

Sampled lot

This is the amount of product represented by the sample. The plant defines the sampled lot. It is the establishment's responsibility to have the data to support that the ground beef from one portion of product is statistically distinguished, relative to contamination with *E. coli* O157:H7, from another portion of production. "Cleanup to cleanup" may be a part of the procedures that the establishment has in place to support statistically distinguishing one portion of production from another. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli* O157:H7. However, "cleanup to cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another. If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment. Often, factors like the plant's coding system, the pathogen of concern, the processing and packaging, the equipment, the plant's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

Sample unit

This is an individual package or container. It may take several sample units to make up one sample, depending upon the amount needed for the analysis. The amount of sample is detailed in various directives. Some samples are made up of more than one sample unit.

Sampling types

The term “sampling” as used in this module implies FSIS sampling. FSIS sampling refers to you physically collecting product that represents a product type and submitting it to a lab for an actual analysis. Whenever plant sampling is discussed, it will be stated as such.

The lab is completely dependent on you to properly collect, prepare, and ship the sample. The forms that accompany each sample must be the correct ones for the sample request and must be accurate and completely filled out. Your role is vital. The information entered on the form becomes part of a legal document.

There are three types of sampling: inspector-generated, OPHS (Office of Public Health Science) directed, and special projects.

Inspector-generated samples are based on suspicion, and the reason for the sampling determines the product/category. If you suspect adulterated product was produced, then you may submit a sample ***after*** getting approval to sample from your Frontline Supervisor (FLS) and receiving an OPHS-generated form. You can no longer use any form but the FSIS Form 10,210-3 (Requested Sample Programs) that you obtain from OPHS.

OPHS directed samples are selected when sample requests are received in the mail. The directed sample requests for microbial analyses are on the Requested Sample Programs form, 10,210-3. (The 10,210-3 soon will be sent electronically rather than through the U.S. mail.) For OPHS directed samples, the product history determines the sampling. OPHS determines to which plants to send sample requests based on seasonality, product types, processing methods, plant histories, and randomness.

Special project samples are taken when FSIS is alerted to a food borne illness outbreak by a state or local government, or when there is a special need.

Workshop I

1. FSIS sampling is done to
   a. verify that FSIS performance standards and regulations are met.
   b. validate HACCP plans and compare results to plant analyses.
   c. generate public support.
   a. monitor in-plant activities.

Matching

	Definitions		Answers
	Sampling initiated by OPHS	A	Raw ground beef components
	A Check to determine that a system is working as intended	B	Aseptic
	Raw ground or chopped beef, hamburger, ground or chopped veal, veal, or beef patties, and patty mix	C	Directed
	Intact or non-intact beef products intended for manufacturing into ground beef product	D	Raw ground beef products
	Not adding pathogenic organisms	E	Recall
	A collection of product that represents a larger group	F	Retain
	The amount of product represented by a sample	G	Sample
	Product is placed under official control in the plant	H	Sampled Lot
	A plant's voluntary removal of product from commerce	I	Verification

Procedure code 05B02

Procedure 05B02, although under the "Economic Sampling" heading, entails microbial analyses with a direct bearing on food safety and public health.

05B02 as it Relates to Food Safety
FSIS verification activities include, collecting and testing raw products for microbial hazards. FSIS Directive 10,210.1, "Unified Sampling Form", lists the products and pathogens and toxins for which FSIS may collect and test samples. For example, FSIS may analyze raw ground beef products, raw ground beef components, and beef patty components for *E. coli* O157:H7.

Since a directed sample request is ***not*** a scheduled procedure, 05B02 is recorded as unscheduled on the Procedure Schedule.

Raw products that fall into 03B currently have a specific sampling program under directed food safety sampling (05B02).

Directed Microbial Sampling for Raw Product	
Products	**Microbial Analyses**
Raw ground or comminuted beef or veal products, including ground beef, hamburger, beef patties, beef patty mix, etc.	*E. coli* O157:H7
Project Number	**Project Name**
MT03/MT04	Raw Ground or Comminuted Beef or Veal (Beef or Veal Only) Federal Program

Steps in Sampling

Step 1: Determine Product to Sample
You determine which product to sample by knowing the plant's processes and how product is labeled. Before collecting a sample, review the notices or directives covering that sample type or program. A directed sample request may have additional instructions printed in block 18 of the Requested Sample Programs form (see Attachment 4).

For directed sample requests, the product/category is specified on the request form 10,210-3. Unless a specific product (e.g., beef patties) is requested, the IIC (Inspector-in-Charge) should oversee sample collection to ensure that different products (as long as it is the same type of product stated on the Requested Sample Programs form) are sampled each time sample request forms are received.

FSIS Directive 10,010.1 was updated because the Agency believed it was necessary to increase its verification efforts. Inspection personnel will collect a sample **whenever** they receive a directed sampling request (FSIS Form 10,210-3) for this sampling project (MT03/04).

Products to Sample
Currently, the only specific raw ***products*** sampled as on-going in directed sampling are ground beef products analyzed for *E. coli* O157:H7. The products that are included in "raw ground beef" are raw (chopped or ground) beef food products made from cattle carcasses (beef and/or veal), such as ground beef, hamburger, veal patties, and beef patty mix that are distributed to consumers as such. (Sampled products may ***contain*** beef derived from advanced meat recovery systems, but advanced meat recovery system products are ***not*** sampled by themselves. Products that contain another type of livestock product in addition to beef (e.g., beef and pork patty) are also not sampled.)

Components to Sample
Additionally, raw ground beef components and beef patty ***components*** may be sampled.

You are only to collect samples of raw ground beef or raw beef patty components that are intended for use in raw non-intact product. The sample request will indicate if you are to sample such product. You may be instructed to collect more than one sample per lot. To determine the intended use of the products, review establishment records and HACCP documents (flow charts, hazard analyses, etc.). In cases where such documents are unclear about the intended user, handle the product as if it were for use in raw non-intact product. Also, if the plant has not identified the intended use or consumers of the finished product, there is noncompliance with 417.2(a)(2).

Step 2: Notify Plant Management
Plant management must be notified whenever a sample of its product is taken. It gives management the option of holding the product represented by the sample pending test results. Inform the plant of the reason why you are taking the sample (routine monitoring, follow-up sampling in response to an *E. coli* O157:H7 positive, a trace-back sample, or follow-up sampling in response to an *E. coli* O157:H7 outbreak). **Recommend** that plant management hold the sampled lot of product. Since the plant may opt to hold the lot, it needs sufficient time to make the necessary arrangements to do so. The purpose of FSIS sampling is to verify the plant is producing unadulterated product.

Inspection personnel need to be familiar enough with the process to realize that in some cases notifying the establishment one day prior to collecting the sample may not be adequate time to allow the establishment to hold all product represented by the sample. If the establishment requests more than a couple days notice prior to collection of the sample, you should contact the District office

or the Technical Service Center for guidance. You should discuss the notification and time frames with plant management ***prior*** to any sample requests being received in order to have an agreed upon notification protocol in place when a sample must be collected.

In the case of raw ground beef product, you must give plant management a handout stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results. (See Attachment 1.) This handout can be discussed at a weekly plant meeting to address these issues with plant management so they are aware of the procedure and protocol you will follow. If the product represented by the verification sample is not voluntarily held, it is subject to voluntary recall, retention, or seizure if the sample is positive for pathogens, including *E. coli* O157:H7.

Step 3: Collect the Sample

If possible, only collect a sample from the current day's production. It needs to be collected during normal production because the sample represents the process. Collect the sample in final packaged form, whenever possible.

FSIS Directive 10,210.1 provides sampling instructions under project numbers MT03 and MT04. For these project numbers, a 1-lb sample of ground beef product is needed, in final packaged form (whenever possible). If the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded (see Attachment 3 for discard reasons). If the plant has freezing as a CCP in its HACCP plan, additional guidance may be provided by OPHS on a case-by-case basis. If the plant irradiates its raw ground beef, then FSIS Directive 7700.1, "Irradiation of Meat and Poultry Products", should be followed.

In most cases, block 4 of FSIS Form 10,210-3 is pre-printed with a ***time frame***. Select the day to collect the sample during the time frame indicated. It has a pre-printed date that tells you when to collect a sample. Usually it has a date in the "within 30 days of" section. That means that by 30 days ***after*** the date printed in the block, you should have collected a sample. ***All*** samples not collected within the designated time frame on the sample request form (e.g., Day of, Week of, Within 30 days after the date printed in the box) are discarded at the labs. Do not send in a sample after the 30 days unless you are directed to do so. If the plant will not produce the targeted product in that time frame, you must send the form back to the lab with an explanation.

4. COLLECT TISSUES/SAMPLES ON		
Day of:	Week of:	Within 30 days of:

All samples are selected ***randomly*** from the type of product requested. The IIC oversees sampling to ensure that different products within the requested product type are sampled each time sample request forms are received. In order for the sample to be representative of a lot, every attempt must be made to avoid taking a sample that is biased (i.e., nonrandom). One of the best ways to ensure an unbiased sample is to randomly select a time to collect the sample after grinding and, whenever possible, in its final packaged form. You can use a random number table or generator to determine that time.

Collect samples in a sanitary manner. You want to assure that the sample is not contaminated from outside sources. When it is not possible to collect the sample in final packaged form, follow instructions in Attachment 6 for aseptic sample collection. Put the sample (intact or not) in a sterile bag provided by the lab.

Put the sample in a secure location. If a sample must be held overnight, it must be refrigerated. If a sample must be held longer than overnight, it must be frozen.

If for whatever reason, the plant decides not to ship the product represented by the sample selected, but to rework it or dispose of it, then you must likewise discard the sample by returning it to the plant. Send in the 10,210-3 to the lab with an explanation of why no sample was sent in block 33 by marking “other” and writing a short explanation.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date.)

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIES/CLASS OR PRODUCE THE REQUESTED PRODUCTS (If checked, plant will be removed from this sampling program.)

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ OTHER (Explain)

Step 4: Packing and Mailing the Sample

If the paperwork is not complete, or if it is missing, or for the wrong product sample, the sample ***will*** be discarded. Be sure the sample and the paperwork match, otherwise the sample is rejected.

All sample forms received ***without*** a collection date are discarded.

Microbiological pathogen samples submitted on FSIS Form 10,210-3 must have Part II, blocks 19, 20, 22, and 28-32 completed. Otherwise the lab discards them.

19. DATE COLLECTED	20.DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

Note: *Block 21 doesn't apply to raw ground beef and/or veal samples.*

28. REMARKS

Note: *Block 28 has additional information and questions you need to answer. Provide the production volume information requested in block 28 of FSIS Form 10,210-3, along with any other requested information.*

29. COLLECTOR'S SIGNATURE	30. *NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

Note: *The badge number is for the positive identification necessary for a traceable chain of custody. For example, if there are two Sam Smiths in FSIS, it is important to identify which Sam Smith sent the sample. Using your badge number does not violate your privacy, but it does supply the necessary positive identification for legal purposes.*

Only one sample should be in a shipping container to avoid confusion. The laboratory does not discard a sample just because two different samples are in the same shipper. If you do include more than one sample, write this information on the Container Seal. However, the labs will discard them if it is not clear which sample goes with which sample form.

Double-check and compare the address on the FedEx Air-bill to make sure it is going to the lab indicated in block 9 of the sample form. The lab will discard the sample if you mail it to the wrong lab.

The shipping containers you receive should have the top and bottom sealed by the lab with red and black striped tamper-evident tape. You will ***not*** receive any tamper-evident tape to use.

Pack the sample in this order.

1. Gel pack
2. Coolboard
3. Sample with paperwork (all in a zip-lock bag)
4. Foam plug
5. Close the shipper with seal (7355-2A – Container Seal)

A frozen gel pack should be added for product that was stored refrigerated or frozen. The piece of cardboard called the coolboard goes on top of the gel pack to separate the gel pack from the sample. Put a small bar code sticker from Form 7355-2 at the top center of the sample form (i.e., paperwork) and put the form in a bag or plastic sleeve. Put another small bar code sticker on the bagged sample. Put the sample and paperwork into the larger Ziploc bag and affix the Identification Label (7355-2B) to the bag. Note that the 7355-2B is a ***label*** rather than a seal and must simply be affixed. There is no need to fold over and seal the bag with the label. The zip-lock bag, containing the bagged sample and the paperwork, is put into the shipper. Filler material is ***not allowed*** in the shipping container. This means that no newspaper, paper towels, etc., can be inside the shipping container to take up any empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. Put any extra unused bar codes into the box so that the lab can account for them, or put them on the Container Seal where they won't cover any written or printed information. Alternatively, if you keep a record of the sample, you can affix the extra bar code to your record. Close up the box and seal it.

For sample integrity, a Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

If it is not possible to collect the sample on the same day that the pre-shipment review will be completed (e.g., product is held off-site prior to completion of the pre-shipment review, or the review is performed at a later date), samples collected from the current day's production must be refrigerated ***or*** frozen (based on instructions in the directives), kept secure, and the mailing postponed until the pre-shipment review is performed. After the plant completes the pre-shipment review, the sample is mailed on the next available day the contract carrier picks up. If you determine that the plant shipped the product without doing a pre-shipment review, immediately mail the sample to the lab (since the product is in commerce) and issue an NR for the pre-shipment recordkeeping noncompliance.

Samples are mailed so they arrive at the lab the next day. Samples should not be held over the weekend if it is avoidable (not more than three days). If the sample is collected and held pending the pre-shipment record review, make a note of this on the sample form for the lab. This will alert the lab as to why you waited to mail the sample. However, if a sample must be held over the weekend (Friday to Monday), it must be frozen. The current contract carrier will ***deliver*** on Saturdays, but not ***pick-up***. A "Saturday Delivery" label must be used. Put a checkmark (√) in the "Saturday Delivery" portion of the delivery airbill or stamp.

FSIS Laboratories

Samples are sent to the appropriate FSIS lab identified on the 10,210-3.

There are three FSIS Technical Service Laboratories. The Eastern lab is in Athens, GA, the Midwest lab is in St. Louis, MO, and the Western lab is in Alameda, CA.

The FSIS labs are responsible for providing the sampling supplies. Whenever supplies are needed, send an e-mail request through Outlook following FSIS Notice 20-04 (see Attachment 5).

Example 1
You receive a sample request from OPHS for project number MT03. You read the information on the 10,210-3 and the related directives. You note the time frame in block 4 of the form. On the appropriate date, you notify plant management that you will be collecting a sample today. You ask what products are being produced that meet the product type requested. You are told by the production manager that today they are producing bulk raw ground beef in 20-lb twist-tie bags, raw hamburger in 2-lb tray packs, raw beef patties packed 12 to a vacuum sealed bag, and raw beef patty mix in 40-lb boxes. You tell the production manager that you will collect a sample from the hamburger. At the time you go out to collect the sample off the packaging line, you notify plant management. A QC person accompanies you out to the line. You wash your hands and then pick up a package off the line. The QC person asks why you selected that package. You tell her it was randomly based on time. You ask her when the pre-shipment review will be done for this product. She says it will be done in the morning. You realize that you won't be able to verify that until tomorrow morning, so you refrigerate the sample according to the directions in FSIS Directive 10,210.1. You put it in the retain cage in the cooler and secure it with a government lock. The following morning you verify that the pre-shipment review was completed and then you pack and FedEx the sample to the FSIS lab listed on the 10,210-3 sample request form.

Workshop II

1. You suspect that a product may be out of compliance. Before taking a sample,
   a. make sure the plant is not aware of the sampling.
   b. contact an EIAO.
   c. get approval from your front line supervisor.
   d. first complete all scheduled procedures assigned for the day.

2. When would a ground beef sample be sent to the lab for an *E. coli* O157:H7 directed sample?
   a. the day before the “use by” date
   b. just prior to packaging
   c. the first day FedEx is available after the pre-shipment review is completed
   d. as soon as the lot is assembled

3. Plant management is notified that you are taking a sample
   a. when you receive the analysis result (either from LEARN or the DO).
   b. if the plant has a good working relationship with FSIS.
   c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
   d. because of the Freedom of Information Act (FOIA).

4. How many samples **should** be submitted per shipping container?
   a. 1
   b. 2
   c. 3
   d. 4

Scenario

You received FSIS Form 10,210-3 requesting a raw ground or beef or veal sample under the MT03 project code. This is the first time you have received this type of sample request.

As a critical thinker, what do you do next?

The instructions tell you to randomly select and aseptically collect an unfrozen one pound sample prior to freezing. The plant receives beef trimmings and chubs of ground beef. The chubs may be added to the beef trimmings and ground, or they may be shipped without any further processing. The ground beef and beef trimmings are ground into ground beef, ground beef patties, raw beef and pork sausage, and cooked meatloaf. The plant has one grinder and does a complete cleaning and sanitizing of the equipment prior to the start of operations each day.

What product do you sample for the *E. coli* O157:H7 project?

When would you notify plant management that you will take a sample?

The plant manager asks you to tell him specifically the time when you will collect the sample so he can stop production after the sample is taken.

How do you respond?

What should you do after you collect and submit the sample?

Step 5: Results

Access LEARN to track your sample receipt and results. LEARN means Laboratory Electronic Application for Results Notification. More information is contained in FSIS Directive 10,200.1. LEARN is a computer application that notifies FSIS personnel and establishment management of the receipt and status of samples sent to FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard, and the results of the analyses when they are completed.

If you click on the correct sample in LEARN, at the bottom of the screen there should be a discard reason/description. This is below the normal area on the screen where results are found. If the sample was discarded, notify the establishment. This is especially important when the plant is holding product.

Microbial analyses results are reported as positive or negative. Some are listed as presumptive, which means that there is evidence to suggest the product is out of compliance, but additional analyses and/or samples are needed to confirm it. LEARN provides immediate notification of sample analyses.

OPHS e-mails sample results to plants that complete FSIS Form 10,230-2, “FSIS Establishment E-mail (Internet) Address Collection Form”, and submit it to OPHS. Even if the establishment receives sample results directly from OPHS, it is still your responsibility to notify the establishment when sample results are received.

Negative

The first lab analysis is accomplished within two days of sample receipt. It is a screening test that identifies the presence of *E. coli* O157:H7. If the screening test is negative, *E. coli* O157:H7 is not present in the sample tested. The negative results are posted in the LEARN system. FSIS resumes normal sampling at that establishment.

Presumptive Positive

If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7 and additional testing is necessary to confirm the result. This second step, called confirmatory testing, is usually accomplished within 5 days of the sample receipt, but can sometimes take longer.

The DO alerts the plant in cases where the lab, using BITES (Biological Information Transfer E-mail System), notifies the DO (prior to posting the information in LEARN) due to a presumptive positive for *E. coli* O157:H7. This ensures that the plant receives this important message if you are not available. The District Office contact will also inform the plant that if the results are confirmed positive, FSIS will collect information regarding specific supplier of the

source materials used in the production of the product that tested positive (confirmed).

Supplier Information
- Name of the establishment
- Point of contact (name, title, e-mail address, and fax number)
- Phone number
- Supplier lot number
- Production date
- Name of supplied material and any additional information to clearly identify the material

If the source materials are imported from a foreign establishment, additional information will be needed by the establishment (country of origin, foreign establishment number, shipping mark, I-house, and bar-coding or other information to aid in identifying the product).

At the time the sample is presumptive positive, the plant should start to gather supplier information.

Positive

Positive results are also on the LEARN system. If positive results are obtained, notify the plant. A DO contact will also alert the establishment.

When a presumptive positive sample is confirmed positive, collect the required supplier information from the plant and e-mail it to the DO contact designated to receive this message. Make a note of any information the plant is unable to provide. Copy your Frontline Supervisor.

Issue an NR for all FSIS positive results under the appropriate ISP HACCP code using the “verification” trend indicator and 417.4 as the relevant regulation. An FSIS test result of a positive for 05B02 sampling is a noncompliance. As soon as possible after the establishment has implemented its corrective action, perform the 02 procedure for the specific production that tested positive. Determine whether or not the plant implements corrective actions that meet the requirements described in §417.3.

Plants are expected to only ship wholesome unadulterated product. The establishment is responsible for determining what product it holds and what it determines to be “affected product”. (FSIS Directive 8080.1, Rev. 4, contains more information related to affected product or “scope”.) If the plant does not control its product, then take a regulatory control action (retain product if it is available or take a withholding action per §500.3(a)(1) if the plant shipped the adulterated product into commerce). If any affected product has left the plant and it is no longer under the plant’s control, notify the DO. A recall may be

recommended. (Documentation and enforcement will be covered in more detail in a later module.)

Plant management must account for all affected products by identifying them and their location. The plant is expected to take corrective actions that meet one of the following requirements:

- 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan, or
- 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan, or if it is addressed in prerequisite programs, or
- 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the SSOP.

The establishment may need to conduct a reassessment of its HACCP plan or reevaluate its SSOP or prerequisite programs to meet these requirements.

If product disposition is to occur off site, verify that the plant maintains appropriate control of the product.

Off-site Product Disposition

Product confirmed positive for *E. coli* O157:H7 may be moved off site for proper disposition, under appropriate controls. Product may be transferred to another official establishment for further processing to destroy the pathogen. Plants may opt to dispose of the product through rendering or disposal in a landfill. Plants may also divert product that is presumptive positive, rather than wait for a confirmation. Presumptive positive product must be controlled just like confirmed positive product. Plants may use their own controls (e.g., company seals) or move the product under FSIS control (e.g., USDA seals or FSIS Form 7350-1, “Request and Notice of Shipment of MPI Sealed Meat/Poultry”). When the product is destined for a landfill or rendering operation, it moves under company controls, because FSIS representatives are not at those locations to remove USDA seals or follow up with FSIS Form 7350-1.

When the establishment moves positive product off-site for disposition, verify the plant that produced the positive product maintains appropriate control of the product at all times, including while it is in transit to the off-site location where the product will either be reworked to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

Conduct the following additional verification activities when you perform your 02 procedure.

- Obtain the name of the receiving official establishment, renderer, or landfill. This includes the name and address for renderers or landfills.

- E-mail your District contact person with the receiving establishment number or the name and address of the landfill operation or renderer (where product

will be further processed). Your DO will contact the DO with jurisdiction over the receiving locations.

- For product destined for a landfill operation or renderer, verify that the establishment will maintain control of the positive product while it is in transit (e.g., through company seals).

- For product being transferred to another official establishment for further processing, verify that either company or FSIS controls are in place.

- Verify that records are available demonstrating the positive product received proper disposition. This includes documentation evidencing proper disposal of the product at the official establishment, landfill operation, or renderer. You cannot complete your HACCP 02 procedure for this specific production until the plant conducts pre-shipment review. The plant cannot conduct the pre-shipment review until it receives documentation from the other official establishment, landfill operation, or renderer showing proper disposal. If you find noncompliance with this, contact the DO. The DO will investigate to determine if the plant committed the prohibited act of offering adulterated product for sale into commerce.

At the plant receiving positive product

If you are the inspection program employee at the plant that receives raw ground beef products, raw ground beef components, or raw beef patty components that tested positive for *E. coli* O157:H7, you have certain verification functions to perform.

When you perform the HACCP 01 or 02 procedures for such products, verify that the plant

- documents receipt of presumptive or confirmed positive product (as per §417.5),
- maintains control of the product, and
- addresses the presence of *E. coli* O157:H7 in its hazard analysis and HACCP plan (includes adequate lethality treatment to destroy the pathogen).

Document all noncompliance as per FSIS Directive 5000.1, Rev. 1.

Follow-up to an FSIS Positive Sample and Follow-up Sampling

When an FSIS sample for raw ground beef product is confirmed positive for *E. coli* O157:H7, issue an NR for HACCP noncompliance, verify the plant's corrective actions, check appropriate decision-making documents, assist in any needed recall, collect supplier information, and conduct an 02 procedure on the specific production that tested positive. You cannot complete the 02 procedure until the establishment has taken corrective actions and the product is properly dispositioned.

If you find no significant problems as a result of conducting the 02 procedure, contact OPHS via Outlook (send to "Sampling Forms – Headquarters") requesting a follow-up sample form (10,210-3). Copy your FLS (Frontline Supervisor) and DO (District contact) on this message. Be sure to include the

- Establishment number
- Number of forms needed (in this case 1)
- Type of sample to be collected (product sample)
- Purpose of the request (follow-up sampling in response to a confirmed positive in raw ground beef)
- Sample form number of the original positive sample triggering this request, and
- DO official approving the request.

You will be given guidance at the time you need to collect the follow-up sample. Specific instructions for the follow-up samples may be provided on the FSIS Form 10,210-3 you receive in answer to your e-mail request, in FSIS Directive 10,210.1, or through your District Office.

Collect the follow-up sample as soon as possible after the plant completes its corrective actions. If the plant delays disposition of the positive product, work with your FLS to determine when it would be appropriate to collect the follow-up sample. Your FLS should give you guidance on how to work with the plant to ensure proper and timely disposal of the product.

If you find regulatory noncompliance while performing the 02 procedure, document it on an NR (as per FSIS Directive 5000.1, Rev. 1). If you find that the plant moved positive product without the necessary controls, or if you find that the plant does not have records documenting proper disposition of the positive product, contact your DO. Collect one follow-up sample as soon as possible after the plant takes corrective actions (request the follow-up 10,210-3 from OPHS as indicated earlier).

You may uncover concerns regarding the adequacy of the HACCP system design when performing the 02 procedure. If so, do not collect a follow-up sample. Notify your FLS. The FLS will determine if it is necessary to have an Enforcement Investigations and Analysis Officer (EIAO) conduct a comprehensive assessment of the plant's total food safety system. If the EIAO concludes that the corrective actions appear appropriate and effective, then the EIAO will contact OPHS for a sample form. You collect the follow-up sample as soon as possible after receiving the form. If the EIAO concludes the corrective actions are inappropriate or ineffective, or if the follow-up sample is also confirmed positive, the DO will give you further guidance on how to proceed.

FSIS verification at establishments producing components

When raw ground beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments that produced the raw ground beef components or the raw beef patty components that were used to produce the positive product. The DO will contact the IIC at the supplying plant. If you are at the ***supplying plant***, remind the plant that the notification is to ensure that the supplier knows that it ***could be*** the source of *E. coli* O157:H7 positive product. It is not a definitive determination that the supplier is the source of the pathogen contamination. The IIC at the supplying establishment will perform a HACCP 02 procedure to verify that the supplier met all regulatory requirements at all CCPs in the HACCP plan for production lots sent to the plant where the positive was found.

You may be instructed to collect samples of raw ground beef components or raw beef patty components. (Follow collection instructions in Attachment 2 of FSIS Directive 10,010.1, Rev. 1, located at the end of this module.) Only collect samples from components that are intended for use in raw non-intact product.

If the component sample is confirmed positive, you perform the same activities as you do for any FSIS confirmed positive sample result. You must verify that the establishment ensures that controls for transporting the positive product are the same as previously described.

Plant-generated Sampling

Some plants may have their own sampling programs for *E. coli* O157:H7. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes produce safe, wholesome unadulterated product. These sampling programs may or may not be included in the plants' SSOP or HACCP plans. Even though these programs may not be included as part of the SSOP or HACCP system, plants are still required to share records and analyses results with you.

Based on the regulatory requirements of 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of such testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, ***on at least a weekly basis***, inspection program personnel must review the results of any testing and of any monitoring activities the plant performed that may have an impact on the hazard analysis. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite programs, contact the Technical Service Center or raise the concern through

supervisory channels. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test results reveal about food safety and whether the design of testing, procedures, or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

Note: *You can collect a sample, with supervisory approval, anytime you suspect noncompliance or have reason to believe that a sample is warranted.*

The plant is not obligated to notify FSIS when it receives a positive sample, but it must take corrective actions that meet the requirements of §417.3 each time a positive result is obtained. The plant must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

Example 2
A plant has its own testing program for *E. coli* O157:H7 for its raw hamburger patties. The plant has not included it as a verification activity in its HACCP plan. In the last test, the result was positive. The plant always holds product pending results. The plant does not need to inform you of its positive result. But, the plant must implement corrective actions that meet the requirements of 9 CFR 417.3. You must verify that the plant took the necessary corrective actions to meet these requirements. You should become aware of the positive from your regular review (at least weekly) of the plant's sampling results or from reviewing corrective action records or observing corrective actions the plant takes.

Example 3
A plant has its own testing program for *E. coli* O157:H7 in its beef trim. The testing is part of the verification of the overall HACCP plan. The plant analyzes the samples while the product is in transit, but still under the plant's control. When the result is received, the plant completes the pre-shipment review. The product is ***not*** in commerce, but in transit. The last test result was positive. The plant must implement corrective actions that meet the requirements of 9 CFR 417.3. Again, you must verify that the plant meets ***all*** four requirements described in 417.3.

Whether the plant brings the product back to the establishment for disposition, or it diverts it for further processing at another official establishment or to a landfill or renderer, the plant must demonstrate control of the adulterated product until that product receives proper disposition. The establishment must provide documents evidencing proper disposition.

When you are aware that there was a positive result you must

- Conduct an 01 or 02 procedure to verify the plant's corrective actions (§417.3(a) or (b)), and
- Issue an NR **only** if the plant fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

***Note**: The HACCP 02 procedure cannot be completed until pre-shipment review, which includes disposition documentation.*

Some plants may opt to divert the product to another official establishment for cooking when they receive a ***presumptive positive*** in their testing program, or to a landfill or renderer. However, the plant is still obligated to meet ***all*** parts of 417.3. It is still required to have proper control of the product while it is in transit for disposition. It also must maintain documentation of appropriate disposition.

When product that is ***presumptive positive or positive*** for *E. coli* O157:H7 is transported to another official establishment for appropriate disposition, the plant sending the product must

- maintain records identifying the official establishment, renderer, or landfill operation that receives the presumptive positive or positive product, ***Note**: If the product is analyzed while in transit, the plant must maintain records identifying the official establishment to which the product is being sent.*
- maintain control of product (company controls or FSIS controls),
- maintain records that indicate product received proper disposition, and
- completes pre-shipment only after it has all disposition records for that particular product.

If you are aware that presumptive positive or positive product is in transit, verify the controls. In addition, e-mail the DO information about the intended product disposition location (establishment number, or name and address of renderer or landfill).

If inspection personnel find noncompliance with the plant's handling of presumptive or confirmed positive product contact the District Office. The DO will investigate to determine it the plant sold or transported adulterated product.

Example 4
The establishment has a finished product sampling program as part of its verification of the HACCP plan for raw ground beef product. Its last sample was presumptive positive.

The plant diverted the product to cooking at its own in-plant cooking operation. It identified all affected product and cooked it separately from its other products. The company utilized a HACCP plan that had been designed specifically for

product known to contain *E. coli* O157:H7 and which contains a CCP for lethality that was validated to eliminate *E. coli* O157:H7. Records demonstrating the positive product received proper disposition are available.

The plant identified the source of the presumptive positive *E. coli* O157:H7 contamination as coming from a new supplier. Plant management required the supplier to demonstrate that validated antimicrobial interventions are implemented in its process before purchasing any other products from that supplier.

The plant includes this certification as a HACCP verification.

Instructional or Disclaimer Statements

Although instructional and disclaimer statements do not affect the samples you collect, you may encounter them while performing your verification duties.

Establishment that Labels the Product
An ***instructional statement*** concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure the pathogen is eliminated or reduced to undetectable levels. Examples of such statements are “for full lethality treatment” (any process that eliminates or reduces *E. coli* O157:H7 to undetectable levels) or “for cooking only” (application of sufficient heat to eliminate or reduce the pathogen to undetectable levels).

A ***disclaimer statement*** concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were **NOT** used in producing the product. An example of such a statement is “product has not been tested for *E. coli* O157:H7”. A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (§417.6).

Instructional and disclaimer statements are not required. They can only be used on product for use at other official establishments (not for use on retail product). The Labeling and Consumer Protection Staff (LCPS) must approve the use of such statements. When LCPS grants sketch approval for instructional statements, LCPS specifies that such statements can only be used on products destined for official establishments that ensure the product receives adequate lethality treatment. When LCPS grants sketch approval for disclaimer statements, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP

plans. Establishments' use of instructional or disclaimer statements is entirely optional.

When you conduct an 04B04 procedure, verify the plant has received sketch approval from LCPS for any instructional or disclaimer statements. The plant is required to maintain these approvals in its labeling records. Issue an NR (reference §317.4(a)) if the plant did not receive sketch approval or does not maintain that sketch approval in its labeling records.

When you conduct a HACCP 01 or 02 procedure, verify that if the plant has instructional or disclaimer statement,

- it is not serving as a control or CCP to address *E. coli* O157:H7,
- it is not justifying the plants determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur,
- its use is reflected in the plant's decision-making documentation or hazard analysis, and
- the plant's HACCP plan for products bearing disclaimer statements includes validated intervention for *E. coli* O157:H7 (in a CCP).

Document noncompliance as per FSIS Directive 5000.1, Rev. 1.

Establishment Receiving Product with Instructional or Disclaimer Statements

If you are assigned to a plant that receives product with instructional or disclaimer statements, when you perform a HACCP 01 or 02 procedure, verify that the plant's HACCP plan addresses the use of product with disclaimer statements as if it may be contaminated with *E. coli* O157:H7, and the plant follows any instructional statements on the incoming product. Document noncompliance as per FSIS Directive 5000.1, Rev. 1.

Retain products processed with incoming product that bear instructional or disclaimer statements if the plant didn't follow the instructional statement, or if its hazard analysis or decision-making documents don't address the use of product with disclaimer statements as if it were contaminated with *E. coli* O157:H7. Retain product if the process is not adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels, or if the product is not intended for further processing that would destroy the pathogen. In addition to issuing an NR, notify the DO of the conditions observed concerning the use of instructional or disclaimer statements. The DO may dispatch an EIAO to conduct a comprehensive food safety assessment or invoke an enforcement action.

Summary

Procedure 05B02 is devoted to directed sampling for food safety concerns. Currently, the microbiological hazard of *E. coli* O157:H7 is of most concern in raw ground beef/veal products, so FSIS is focusing on analyses for that organism in that product.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Workshop III

1. What options does the plant have regarding disposition of product that tested positive for a pathogen but did not leave the plant's control? (Choose ***all*** that apply.)

    a. destroy product
    b. divert product for cooking
    c. relabel product
    d. send the product to a landfill or renderer

2. When will you collect samples of raw ground beef components or raw beef patty components? (Select all that apply.)

    a. Automatically after a positive of a raw ground beef product sample taken by FSIS
    b. Only when directed to do so
    c. Only when the establishment does not take the appropriate corrective actions
    d. After the establishment takes the appropriate corrective actions

3. All instructional statements and disclaimer statements related to *E. coli* O157:H7 must have sketch approval from LCPS.

    a. True
    b. False

4. Instructional statements are intended for household consumers.

    a. True
    b. False

5, Select which products you would sample when directed to collect a sample of raw ground beef product.

    a. Hamburger
    b. Ground beef
    c. Beef patties
    d. Ground beef patties
    e. Beef breakfast sausage
    f. Ground beef and pork mix for meatloaf

6. Select which raw ground beef components or raw beef patty components may potentially be sampled for *E. coli* O157:H7 by FSIS.

    a. Weasand meat
    b. Beef cheek meat
    c. Beef hearts
    d. Beef head meat
    e. Beef trim
    f. Beef from AMR systems
    g. Lean finely textured beef
    h. Partially defatted beef fatty tissue

7. If the plant sends presumptive positive product for *E. coli* O157:H7 to a landfill, what are the requirements to do so?

8. If the plant sends presumptive positive product for *E. coli* O157:H7 to a landfill, what does the CSI do?

9. Which products, when confirmed positive for E. coli O157:H7 are considered adulterated?

    a. Mechanically tenderized beef steak
    b. PDBFT for use in raw beef patties
    c. Beef trimmings for use in grinding
    d. Beef subprimals boned for use in raw ground beef
    e. Raw ground veal patties

Scenarios

1. The establishment where you are assigned slaughters and fabricates beef. It samples its own trimmings as a prerequisite program. On Thursday afternoon, you remembered that, according to FSIS Directive 5000.2, you are to review such records on at least a weekly basis. You go to the office where the records for the prerequisite program are kept and review the sampling results. You notice that on Monday morning, the trim tested from the previous Wednesday was confirmed positive for *E. coli* O157:H7. What are your responsibilities in this scenario?

2. Last week, you submitted a sample of the plant's raw ground beef patties to the FSIS lab. Three days ago you notified the plant that the sample was presumptive positive. Today, when you arrived at the plant, the plant manager told you that he'd been informed by the District Office that the sample was confirmed positive. What are your responsibilities in this scenario?

ATTACHMENT 1

Notice to Give Plant Management When a Sample is Taken

To Establishment Manager:

X The inspector will be taking a sample of your Ready-to-Eat meat and/or poultry product or raw ground beef product to be tested for microbial hazards. Sampling is one component of verifying your HACCP system.

X To protect public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

X Most negative results are available within 3 days; confirmed positive results may take up to 8 days. Results will be provided to you be the inspector or the District Office. For results of future samples, you can receive results by e-mail (contact your District Office for a copy of FSIS Form 10,230-2).

X If a recall is needed, FSIS expects you to initiate the recall in a timely fashion—usually the same day. See FSIS Directive 8080.1 for further details.

X It is your responsibility to determine the amount of product represented by the sample. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. See FSIS Directives 10,240.2 Rev. 1 and 10,010.1.

X If a test result is positive, and you have distributed the product, FSIS will request that you conduct a recall. FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

ATTACHMENT 2

Resources

Currently, there are several directives associated with microbial sampling of raw products that fall into the 03B, 03C, and 03J process categories. This list is current as of 6/17/04. You should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ⇒ All Public Folders ⇒ Agency Issuances ⇒ Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the "What's New" page.

Selected FSIS Sampling References for Raw Product (03B)		
FSIS Directive Number	**Directive Title**	**Directive Date**
5000.1, Revision 1	Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations	3/03
5000.2	Review of Establishment Data by Inspection Program Personnel	3/04
7355.1, Rev 2	Use of Sample Seals for Laboratory Samples and Other Applications	12/3/02
7700.1	Irradiation of Meat and Poultry Products	2/00
8080.1, Rev 4	Recall of Meat and Poultry Products	3/04
10,010.1, Revision 1	Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef	3/04
10,200.1	Accessing Laboratory Sample Information via LEARN	7/19/01
10,210.1, Amend 5	Unified Sampling Form	7/1/02
10,230.2, Amend 1	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses	9/4/92
10,600.1	Sample Shipment Procedures	10/6/83

"Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" are at http://www.fsis.usda.gov/FSIS_Employees/Compliance_Guides_Index/index.asp

ATTACHMENT 3

Discard Reasons

Only those reasons that may apply to raw samples are listed here. The codes are not given in this table since they are used for tracking purposes. Your frontline supervisor has access to this information and monitors the number of discarded samples. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

No Sample Received with Form
Collected Outside Scheduled Time Frame
Temperature Too High
Tissue/Sample Spoiled/Rancid
Container Damaged
Wrong Tissue/Sample for Requested Analysis
Insufficient Tissue or Sample
Delayed Shipment
Shipped on Friday w/o Saturday Delivery label
Original Form Not Submitted w/Sample
Target Tissue Not Received
No Form Received with Sample
Original Form Altered by Sample Submitter
Laboratory Problem*
No Gel Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
Sent to Wrong Lab
Sample ID # on Bag does not match ID # on Form
Security Seal Missing or Not Intact
No Accredited Lab Tests Performed
Headquarters/ TSC/DO Discard
Sampling Instructions Not Followed

ATTACHMENT 4

Internal lab code here	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **REQUESTED SAMPLE PROGRAMS** ☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE	*Barcode here* 1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS

2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/ DISTRICT	6 STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Wthin 30 days of:			

8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)	9. NAME & ADDRESS OF RECEIVING LABOATORY

10. SLAUGHTER CLASS CODE	11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED

14. PROJECT NO.	15. COUNTRY OF ORIGIN	16. COUNTRY COPY	17. FOREIGN EST. NO.

18. ADDITIONAL INSTRUCTIONS

PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24)

26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE	*27. ANIMAL ID (Tag No.)*

28. REMARKS

29. COLLECTOR'S SIGNATURE	*30. NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

PART III, LABORATORY RECEIPT INFORMATION

34. SAMPLE PACKAGING ☐ 3034 Intact Package ☐ 3035 Non-intact Package	35. SAMPLE RECEIPT DATE

36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERTURE

39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)

ATTACHMENT 5

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	20-04	3/19/2004

REQUESTING SAMPLE COLLECTION SUPPLIES AND FORMS

If inspection program personnel need sample collection supplies and forms, email the laboratory designated on your sample request form, or the lab to which inspection program personnel will be sending the sample. In order for the lab to promptly respond, the message must contain:

- establishment number
- daytime phone number
- project identification (if applicable)
- supplies needed

If a daytime phone number is not available, the laboratory may need to reply by email. Supplies will be sent via FedEx to the Overnight Mail address in the PBIS database for this establishment.

NOTE: Inspection program personnel should verify that the mailing address in the PBIS plant profile is current.

Program personnel are to order laboratory sample collection supplies and forms by sending the requests to the following Outlook email addresses:

Sampling Supplies – Eastern Laboratory
Sampling Supplies – Midwestern Laboratory
Sampling Supplies – Western Laboratory
Sampling Forms - Headquarters

State inspectors without FAIM computers, should contact their state coordinators, who will email the following addresses from outside the FSIS Exchange server:

SamplingSupplies-EasternLab@fsis.usda.gov
SamplingSupplies-MidwesternLab@fsis.usda.gov
SamplingSupplies-WesternLab@fsis.usda.gov

The District Inspection Coordinator may also be contacted to assist inspection program personnel without FAIM computers to send emails to the appropriate Outlook mailbox.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; TSC; FSIS Laboratories; Import Offices	**NOTICE EXPIRES:** 4/1/2005	**OPI: OPPD**

If inspection program personnel need additional copies of FSIS Form 10,210-7 to complete a *Salmonella* sampling set, send an Outlook message to Sampling Forms - Headquarters. All other FSIS sample forms (i.e., 10,600-1) should be ordered through the regular FSIS Field Supply system at Beltsville (1-800-714-8335).

For directed sampling, the FSIS Form 10,210-3 cannot be regenerated if lost. If FSIS Form 10,210-3 is not received within the 30-day sample collection period, inspection program personnel are to send an e-mail to the SamplingForms–Headquarters mailbox and copy the Front-line Supervisor. Inspection program personnel should include the establishment number, the project, the laboratory, the form number if available, and are to request that the sample request form be coded as “never received.”

Direct questions regarding these procedures to the Technical Service Center.

/s/ Philip S. Derfler

Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 6
This is a note accompanying sampling supplies.

FOOD SAFETY AND INSPECTION SERVICE SAMPLING PROGRAM
E. coli O157:H7 IN RAW GROUND BEEF
MT03 AND MT04

Recommendations For Collecting Samples Aseptically

Samples taken for microbiological analysis require the application of stringent techniques to assure that the sample is not contaminated from outside sources.

- Wash and scrub hands thoroughly to the mid-forearm, using anti-bacterial hand soap (and sanitizer at 50 ppm chlorine equivalency if available).
- Open “whirl-pack” type bag that was sent with this sample collection kit according to FSIS Directive 10230.2, Part. Two.
- Peel open package of sterile gloves from top without contaminating the exterior of the gloves.
- Remove the glove by holding it from the wrist side opening inner surface, avoid <u>any</u> contact with the outer surface of the glove.
- Insert hand without puncturing the glove.
- <u>Do not touch anything</u> with the exterior of the glove except the sample.
- If you have any concern that the glove may be contaminated, discard that glove and use another sterile glove.
- With the gloved hand, collect the sample. Place the sample into the opened bag.
- Remove and discard the glove and close the bag as described in FSIS Directive 10230.2. Label the bag and package for shipping according to directions on form 10,210-2.

LW-A-0030.00
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ATTACHMENT 7

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS DIRECTIVE	10,010.1, Revision 1	3/31/04

MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR *Escherichia coli* O157:H7 IN RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS

NOTE: *FSIS PESONNEL ARE NOT TO IMPLEMENT THIS DIRECTIVE UNTIL MAY 17, 2004*

Part I – General

I. PURPOSE

This directive provides Food Safety and Inspection Service (FSIS) inspection program personnel, program investigators, and import inspection personnel instructions for sampling raw beef products as part of verification testing for *Escherichia coli* O157:H7 (*E. coli* O157:H7) to ensure the protection of public health. It also outlines actions FSIS will take when a raw ground beef product sample, raw ground beef component sample, or raw beef patty component sample is found to be positive for *E. coli* O157:H7. Attachment 1 provides questions and answers for further clarification.

II. CANCELLATION

FSIS Directive 10,010.1, dated 2/1/98
FSIS Notice 11-03, dated 4/18/03
FSIS Notice 47-02, dated 11/20/02

III. REASONS FOR REISSUANCE

This directive has been rewritten in its entirety to be consistent with the Agency's current policies regarding *E. coli* O157:H7. No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. This directive provides new instructions: 1) for the policy that non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated; 2) for follow-up actions taken after an initial FSIS sample tests positive; and 3) for verifying the control of beef products that are presumptive positive or positive for *E. coli* O157:H7.

IV. REFERENCES

Federal Meat Inspection Act
9 CFR 318.2, 325.10, 416, 417, and 500
FSIS Directives 5000.1, Revision 1, 5000.2, and 8080.1, Revision 3
Federal Register Notices: Policy on Beef Products Contaminated with *E. coli* O157:H7 (64 FR 2803, 1/19/99); Recent Developments Regarding Beef Products Contaminated with *Escherichia coli* O157:H7; Public Meeting (65 FR 6881, 2/11/00); Availability of and Request for Comment on FSIS Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef (66 FR 55912, 11/05/01); and *E. coli* O157:H7 Contamination of Beef Products (67 FR 62325, 10/7/02).

V. BACKGROUND

Non-intact raw beef products contaminated with *E.* coli O157:H7 are adulterated. Non-intact beef products include ground beef; beef that has been injected with solutions; beef that has been mechanically tenderized by needling, cubing, Frenching, or pounding devices; and beef that has been reconstructed into formed entrees. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated. Establishment records and HACCP documents (e.g., the flow chart and hazard analysis) should identify the intended use of intact raw beef products. Manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts are removed) are an example of intact raw beef product that may be intended to be used for non-intact product. Raw beef products contaminated with *E. coli* O157:H7 may, however, be further processed at official establishments to destroy the pathogen.

On October 7, 2002, FSIS published a notice requiring establishments that had not already reassessed their Hazard Analysis and Critical Control Point (HACCP) plans for raw beef products in light of relevant *E. coli* O157:H7 data to do so to determine whether *E. coli* O157:H7 contamination was reasonably likely to occur in their production process for raw beef products (67 FR 62329). In that notice, FSIS advised that it intended to scrutinize very closely the hazard analyses and HACCP plans of those slaughter or deboning establishments that had conducted a reassessment and decided that an intervention was not necessary. Also in that notice, FSIS stated that establishments receiving product for grinding should address *E. coli* O157:H7. FSIS explained that these establishments could employ validated Critical Control Points (CCPs) in their HACCP plans to address *E. coli* O157:H7, or the establishments could incorporate purchase specifications in their HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs to prevent *E. coli* O157:H7-contaminated product from entering their establishments.

This directive focuses on raw ground beef products and the beef products that are used to produce raw ground beef products. These products will be the focus of FSIS' verification sampling program for *E. coli* O157:H7. Products that FSIS may sample are listed in Parts II and VI.

This directive discusses the significance of a finding that a sample is "presumptive positive." A sample is presumptive positive when analytical steps of microbiological analysis indicate the strong possibility that *E. coli* O157:H7 is present, but additional steps are needed to confirm the presence or absence of the organism.

A sample is confirmed to contain the bacterial isolate of *E. coli* O157:H7 through testing by either FSIS or non-FSIS laboratories when biochemical, serological, or genetic testing results in a finding of *E. coli* Serotype O157:H7, O157:H7:NM (nonmotile), or O157:H7-indeterminate.

FSIS recognizes that many establishments test their raw ground beef products, raw ground beef components, and raw beef patty components for *E. coli* O157:H7. The Agency applauds and encourages this practice. FSIS points out, however, that if an establishment finds a sample of one of these products to be presumptive positive for *E. coli* O157:H7, that product would only be allowed to move off site under appropriate controls for proper disposition at official establishments, landfill operations, or renderers. If the establishment's confirmation testing finds the sample negative for the pathogen, that product may be shipped in commerce under normal procedures. Product that is confirmed positive for *E. coli* O157:H7, through FSIS or establishment testing, may also be moved off site under appropriate controls for proper disposition. If product is confirmed positive, or is presumptive positive and no additional testing confirmed the product negative, such product destined for an official establishment for further processing that will destroy the pathogen would have to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1). Such product destined for a landfill operation or renderer would have to move under company control.

According to 9 CFR 325.10, if product is found to be adulterated or misbranded after it has been transported from an official establishment, transportation back to the establishment that originally produced the product or to another official establishment must be authorized. According to 9 CFR 318.2(d), inspection program personnel must place a U.S. retained tag at the time of reinspection on all products suspected of being adulterated. FSIS will allow product that is positive or presumptive positive for *E. coli* O157:H7 to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1), rather than as required in 9 CFR 325.10 and 318.2(d) to facilitate proper disposition of product that may be adulterated with *E. coli* O157:H7. FSIS intends to modify these regulations to reflect this policy.

Part II -- Inspection Program Personnel Responsibilities for Collecting Raw Ground Beef Product Samples from Official Establishments

A. What comprises raw ground beef products?

Raw Ground Beef Products: Raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix. A raw ground beef product that contains any amount of beef product derived from advanced meat recovery (AMR) systems is considered a raw ground beef product. Raw product comprised only of beef from AMR systems is not considered a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component (see Part VI of this directive). Ground or chopped products made from both beef and other meat or poultry products and beef sausage products are not subject to FSIS' *E. coli* O157:H7 sampling and testing.

B. How is raw ground beef product sampling conducted at official establishments?

1. When the Office of Public Health and Science (OPHS) schedules samples to be taken at an establishment, OPHS will send the Inspector-in-Charge (IIC) FSIS Form 10,210-3, "Requested Sample Programs." OPHS will send the form electronically in the near future. Specific information for the sample to be collected will be included on the sample request or in revisions to FSIS Directive 10,210.1, under the appropriate project.

2. Inspection program personnel may be instructed to collect more than one sample per lot in certain circumstances (e.g., if FSIS has reason to believe that product is at high risk of being contaminated with *E. coli* O157:H7 because of illnesses or outbreaks that may have been associated with the establishment, or because the establishment or its suppliers have previously produced product that tested positive in FSIS-collected verification samples for *E. coli* O157:H7).

3. Before collecting samples, inspection program personnel are to notify official establishment management that they will be collecting a sample and are to provide enough time for the establishment to hold the sampled lot. Inspection program personnel are to inform the establishment of the reason they are taking the sample (e.g., routine FSIS verification testing, follow-up sampling in response to an *E. coli* O157:H7 positive, traceback sampling, or follow-up sampling in response to an *E. coli* O157:H7 outbreak).

4. Inspection program personnel collect samples from the current day's production, and the samples should be, whenever possible, in their final packages. Samples should not be sent to the laboratory until the establishment has completed pre-shipment review for that lot. If product from final packages is not available for

sampling, inspection program personnel should collect an aseptic sample. Products should be held under security following established Agency controls.

5. If a sample must be held overnight, it must be refrigerated. If a sample must be held longer than overnight, it must be frozen.

6. After the establishment completes the pre-shipment review, inspection program personnel should prepare the sample to be sent to the laboratory on the first available Federal Express pick-up.

Part III – Supplier Information

A. What actions does FSIS take when there is an FSIS presumptive *E. coli* O157:H7 positive for a raw ground beef product sample?

1. Every FSIS verification sample that is eventually confirmed positive by FSIS for *E.* coli O157:H7 goes through three stages of analysis. The results of each stage are reported to IIC's on LEARN. These samples are initially screened and, as appropriate, are reported as "Potential Positives." At the next stage, based on laboratory results, some samples are reported as "Presumptive Positives." Because most "Presumptive Positives" are eventually confirmed, the contact person in the District where the establishment is located needs to immediately inform the establishment that the sample is a "Presumptive Positive." At the same time, the District contact person also informs the establishment management that if the results are confirmed positive, FSIS will collect the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

a. name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment;

b. supplier lot number; and

c. production date, name of supplied material, and any additional information to clearly identify the material used to the management of the supplying establishment.

2. If the source materials are from a foreign establishment, the District contact person should inform the establishment that FSIS will also collect the following information, should the product be confirmed positive for *E. coli* O157:H7:

a. country of origin;

b. foreign establishment number;

c. shipping mark;

d. I-house; and

e. barcoding or any other information that identifies the origin of the product.

3. The District contact person advises the establishment that it should begin to gather the information above, along with distribution information.

B. What information does FSIS collect when a raw ground beef product sample collected by FSIS for verification testing at an official establishment is confirmed positive for *E. coli* O157:H7, and whom does FSIS notify concerning the positive?

1. When a sample is confirmed positive, inspection program personnel collect from the establishment the information in Part III. A. Inspection program personnel make note of any information that the establishment is unable to provide.

2. Inspection program personnel forward the information by e-mail to the designated DO contact, with a "cc" to the front-line supervisor.

3. The DO will access the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), open a case file for the incident, and follow STEPS procedures.

4. STEPS automatically e-mails the DO that has jurisdiction over the supplying establishment. The DO notifies the IIC at the supplying establishment to perform a HACCP 02 and other activities described in Part VI.

5. The DO notifies all of the supplying establishments in the District, by telephone, of the positive finding and provides the suppliers the production date for the product that the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot. The DO documents the date and time of this oral notification in the STEPS system.

6. After all necessary information on the supplying establishment has been entered into the STEPS system, the DO reviews the information in the STEPS system and sends an e-mail notification to the supplier about the *E. coli* O157:H7 positive product.

7. The supplier information is maintained within the STEPS system and is maintained on FSIS' network. Users must be given access to this site.

NOTE: If the confirmed positive sample came from product which was made, in whole or in part from imported product, the DO provides information about the supplier to the Office of International Affairs (OIA), Import-Export Programs Staff, by telephone, and documents the date and time of this oral notification in the STEPS system. The DO then provides information about the supplier to OIA, Import-Export Programs Staff, through an e-mail message to importexport@fsis.usda.gov. OIA, in turn, forwards this information to the head of the inspection service in the country where the supplying establishment is located.

Part IV – Enforcement Actions in Official Establishments

A. What actions do inspection program personnel take if an FSIS sample taken from an official establishment is confirmed positive for *E. coli* O157:H7?

1. The DO is notified of a positive through the Biological Information Transfer and E-mail System (BITES).

2. Inspection program personnel, the DO, and Recall Management Staff (RMS) work together to determine the necessity of product retention, detention, or recall. The Technical Services Center (TSC) and OPHS may also serve as technical resources to assist in the decision making process. The DO will contact inspection program personnel and program investigators as necessary (see FSIS Directive 8080.1, Revision 3).

3. As set out in FSIS Directive 5000.1, Revision 1, inspection program personnel are to:

a. issue an NR under the appropriate 03 ISP code using the “verification” trend indicator; and

b. as soon as possible after the establishment has implemented its corrective action, perform a HACCP 02 procedure for the specific production that tested positive for *E. coli* O157:H7 and verify that the establishment implements corrective action that meets the requirements of:

i. 9 CFR 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan;

ii. 9 CFR 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan or if it is addressed in prerequisite programs; or

iii. 9 CFR 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the Sanitation SOPs.

4. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product.

5. If product disposition is to occur off site, inspection program personnel are to verify that the establishment that produced the positive product maintains appropriate control of the product by conducting the following activities when performing the 02 procedure:

a. obtaining the identity of the official establishment or obtaining the name and address of any renderer or landfill that will receive the product;

b. notifying, through e-mail, the contact person in the District that covers the establishment that produced the positive product that adulterated product is being transferred and providing the DO contact person the establishment number of the establishment where disposition will occur or the name and address of the landfill operation or renderer. The District contact person will notify the District where the establishment that will further process the product, landfill operation, or renderer is located, if the establishment, landfill operation, or renderer that is to receive the product is located in another District;

c. for product being transferred to a landfill operation or renderer, verifying that the establishment will maintain control of the positive product while it is in transit (e.g., through company seals);

d. for product being transferred to an official establishment, verifying that either 1) the establishment that produced positive product will maintain control of the product while it is in transit (e.g., through company seals) or 2) the product will move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1); and

e. verifying that records are available that show that the positive product received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, landfill operation, or renderer where disposition occurred. The HACCP 02 procedure at the establishment that produced the positive product cannot be completed for this specific production until the establishment has conducted pre-shipment review of the corrective action record and has received documentation evidencing proper disposal from the official establishment where disposition occurred or landfill operation or renderer where disposition occurred.

6. If inspection program personnel find noncompliance with paragraph 5, they are to contact the DO. The DO will investigate to determine whether the establishment

committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

Part V – Follow-up Sampling

A. Are FSIS follow-up samples taken at official establishments after an FSIS-sample of raw ground beef is confirmed positive for *E. coli* O157:H7?

1. If inspection program personnel identify no significant problems through the HACCP 02 procedure (see Part IV. A. 3. b.), inspection program personnel are to contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up verification sample. Inspection program personnel should copy (CC) their front-line supervisor and the DO designated representative on their e-mail message. The request must include the establishment number, the number of forms (in this case 1), the type of sample to be collected (i.e., a product sample), the purpose of the request (i.e., follow-up sampling in response to a confirmed positive in raw ground beef), the sample form number of the original positive sample triggering this request, and the DO official approving the request. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, Requested Sample Programs, or in revisions to FSIS Directive 10,210.1, under the appropriate project. Inspection program personnel should collect the follow-up sample as soon after the establishment has taken its corrective action as possible. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

2. If inspection program personnel identify regulatory noncompliance, they should document the noncompliance in accordance with FSIS Directive 5000.1, Revision1, Chapter IV. If inspection program personnel find that the establishment may have moved positive product without appropriate controls or if they find the establishment may not have records showing that positive product received proper disposition, they should contact the DO. Inspection program personnel should also collect one follow-up sample as soon after the establishment has taken its corrective action as possible. Inspection program personnel are to contact OPHS so a form can be sent for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

3. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine when it would be appropriate to collect the follow-up sample and how to work with the establishment to ensure proper and timely disposal of the product.

4. If the inspection program personnel have concerns regarding whether the design of the HACCP system is adequate to ensure food safety, they should not collect a follow-up sample. They should notify their front-line supervisor, who will determine whether it is necessary to bring in an Enforcement Investigations and Analysis Officer (EIAO) to the establishment to conduct a comprehensive assessment of the food safety systems. If the EIAO determines that the establishment's corrective actions appear to be appropriate and effective, the EIAO will contact OPHS so a form can be sent to inspection program personnel for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. Inspection program personnel are to take the sample as soon as possible after they receive the form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

5. If a follow-up sample is found positive, the DO is notified through BITES, and the DO will determine the appropriate follow-up action.

6. If the EIAO determines that the corrective actions are inappropriate or ineffective, the EIAO will recommend an enforcement action as described in 9 CFR 500.3 or 500.4 (e.g., Notice of Intended Enforcement (NOIE), withholding, or suspension).

7. If the District Office decides to either defer a decision on suspending the establishment, or a suspension action is taken and then put into abeyance (see FSIS Directive 5000.1, Revision 1, Chapter IV), FSIS will conduct follow-up sampling to verify that the corrective action taken by the establishment is appropriate and effective. The DO will determine the number of follow-up samples. Guidance on how to determine the number of follow-up samples will be provided to the DO. The DO should contact OPHS so the appropriate number of forms can be sent to inspection program personnel for the collection of follow-up verification samples. See Part V. A. 1., for information on e-mailing OPHS to request follow-up sampling forms. The guidance is designed to provide enhanced statistical confidence for finding low levels of *E. coli* O157:H7 but is not designed to provide validation of the establishment's food safety system.

PART VI - FSIS' Verification Activities at Establishments Producing Raw Ground Beef Components or Raw Beef Patty Components

A. If FSIS confirms raw ground beef product at an official establishment or retail facility positive for *E. coli* O157:H7, and a second official establishment supplied the product used to produce the ground product, what verification activities does FSIS conduct at the supplying establishment?

The IIC at the supplying establishment ensures that the inspection program personnel perform a HACCP 02 procedure to verify that the establishment met the applicable regulatory requirements at all CCPs in the HACCP plan (monitoring, verification, recordkeeping, corrective actions, and reassessment) for the production lots sent to the establishment or retail facility where FSIS found the positive. If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision1, Chapter IV.

B. If a grinding establishment or retail facility receives incoming product for grinding, and FSIS finds the raw ground product positive for *E. coli* O157:H7, will FSIS test product from suppliers? If so, how do inspection program personnel collect samples?

1. When FSIS conducts sampling at official establishments or at retail, and a sample tests positive for *E. coli* O157:H7, FSIS may test raw ground beef components and raw beef patty components at the supplying establishment.

2. If inspection program personnel are requested to collect raw ground beef components or raw beef patty component samples, they are to follow the instruction in Part II of this directive and collect samples as described in Attachment 2. The types of product inspection program personnel may collect are:

Raw Ground Beef Components: These components include raw esophagus (weasand) meat, head meat, and cheek meat; beef manufacturing trimmings (e.g., 90/10, 85/15, 75/25, 65/35, 50/50); boneless beef; beef from AMR systems; and lean finely textured beef (LFTB).

Raw Beef Patty Components: These components include all the components listed above in Raw Ground Beef Components, as well as partially defatted chopped beef (PDCB), finely textured PDCB; heart; and partially defatted beef fatty tissue (PDBFT).

3. Also, inspection program personnel are to only collect samples of raw ground beef components or raw beef patty components that are intended for use in raw non-intact product. To determine the intended use of the products, inspection program personnel are to review establishment records and HACCP documents. In cases where the establishment records and HACCP documents (e.g., flow chart and hazard analysis) are unclear about the intended user, FSIS will handle the product as if it were intended for use in raw non-intact product. If the establishment has not identified the intended use or consumers of the finished product, the establishment is out of compliance with 9 CFR 417.2(a)(2).

C. If FSIS finds raw ground beef product at an official establishment positive for *E. coli* O157:H7, and the ground product was derived from raw ground beef components produced at the same establishment, would FSIS sample raw ground beef components at that establishment?

FSIS may sample and test raw ground beef components at an establishment that produces raw ground beef products from such components if FSIS finds the ground beef product positive. If instructed to sample such products, inspection program personnel should follow the sampling procedures in Part VI. B.

D. What enforcement actions do inspection program personnel take if FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7?

Inspection program personnel are to follow the instructions in Part IV. A. The enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7 are the same as the enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef product positive for *E. coli* O157:H7. Similarly, the controls necessary for movement of presumptive positive or positive raw ground beef products are also necessary for movement of presumptive positive or positive raw ground beef components or raw beef patty components.

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PART VII – Inspection program personnel responsibilities related to an establishment's testing of product for *E. coli* O157:H7

A. Can establishments conduct pre-shipment review for product that is not at the producing establishment?

FSIS has taken a consistent position that establishments can conduct pre-shipment review when the product is at locations other than at the producing establishment provided that the product does not leave the control of the producing establishment. Some establishments analyze samples for *E. coli* O157:H7 while the product is being moved but is still under the establishment's control. FSIS is providing the establishments the flexibility to move this product prior to pre-shipment review being conducted when the establishment is conducting testing for *E. coli* O157:H7 and maintains control of the product. FSIS has instructed inspection program personnel that they have access to the results of any testing and of any monitoring activities that are performed that may have an impact on the establishment's hazard analysis (FSIS Directive 5000.2). Inspection program personnel must review these results on at least a weekly basis.

B. What do inspection program personnel verify if an establishment conducts verification testing for *E. coli* O157:H7?

1. Inspection program personnel are to review the records associated with any *E. coli* O157:H7 testing conducted by an establishment. If inspection program personnel find a presumptive positive or confirmed positive *E. coli* O157:H7 result in the testing records, they should verify that the establishment is implementing corrective actions that meet the regulatory requirements as part of a HACCP 02 procedure as described in Part IV.

2. If establishment records show that the establishment transports product that it has found presumptive positive or positive for *E. coli* O157:H7 to another establishment for appropriate disposition, or if establishment records show that the establishment moves product before *E. coli* O157:H7 test results become available, inspection program personnel should verify that the establishment—

a. maintains records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;

b. maintains records identifying the official establishment that is to receive product for which results are pending;

c. maintains control of product that is destined for a landfill operation or renderer while the product is in transit (e.g., through company seals);

d. maintains control of product that is destined for an official establishment while the product is in transit (e.g., through company seals) or ensures such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

e. maintains records that show that presumptive positive or positive product, including product that moved pending test results, received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, renderer, or landfill where disposition occurred; and

f. completes pre-shipment review for product from a lot that has tested positive or presumptive positive and that was moved pending test results only after it has the records described in paragraph e. for that particular product.

3. If inspection program personnel are aware that an establishment has found product presumptive positive or positive for *E. coli* O157:H7, and that the establishment is currently moving the product for further processing to destroy the pathogen or for destruction, they should verify that the establishment moves the product using the appropriate controls identified in Part VII. B. 2. Inspection program personnel should

also notify the DO where the establishment that produced positive or presumptive positive product is located, through e-mail, of the establishment number or name and address of the renderer or landfill operation that is to receive the product. The DO contact person will notify the contact person in the District where the establishment, landfill operation, or renderer that is to receive the product is located, if that establishment, landfill operation, or renderer is located in another District.

4. If inspection program personnel find noncompliance with Part VII. B., 1., 2., or 3., they should contact the DO. The DO will investigate to determine whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

5. The HACCP 02 procedure for a specific production at the establishment that produced the positive or presumptive positive product cannot be completed until that establishment completes pre-shipment review, including review of the corrective action record, and has received documentation evidencing that product has been properly disposed of from the official establishment where disposition occurred or renderer or landfill operation where disposition occurred.

NOTE: When an establishment tests product, a presumptive positive or positive result alone does not warrant an NR. Inspection program personnel are only to issue an NR in response to an establishment's presumptive positive or positive finding if the

establishment fails to take the appropriate actions to meet the requirements in 9 CFR 417.3.

PART VIII – Receiving raw ground beef products, raw ground beef components, and raw beef patty components that are positive for *E. coli* O157:H7

What should inspection program personnel do at an establishment that receives raw ground beef products, raw ground beef components, and raw beef patty components that FSIS or an establishment has found positive for *E. coli* O157:H7*?*

When inspection program personnel perform a HACCP 01 or 02 procedure at an establishment that has received product from a lot that was found positive for *E. coli* O157:H7 product, they are to verify that:

1. the establishment documents the receipt of presumptive positive or positive product, as required under 9 CFR 417.5;

2. the establishment maintains control of the product; and

3. *E. coli* O157:H7 is addressed in the establishment's hazard analysis and HACCP plan, so that the positive product will receive an adequate lethality treatment to destroy the pathogen.

If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision 1, Chapter IV.

Part IX -- Verification Procedures Involving Instructional or Disclaimer Statements Concerning *E. coli* O157:H7

A. What is an instructional or disclaimer statement concerning *E. coli* O157:H7?

1. An instructional statement concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples of instructional statements concerning *E. coli* O157:H7 in raw ground beef components, raw beef patty components, and raw ground beef products may include, "for full lethality treatment" or "for cooking only." "Cooking" is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate *E. coli* O157:H7 or reduce the pathogen to an undetectable level, and "full lethality treatment" may be cooking or another process that eliminates *E. coli* O157:H7 or reduces the pathogen to an undetectable level, such as fermentation or salt curing.

2. A disclaimer statement concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were NOT used in the production of the product. An example of a disclaimer statement concerning *E. coli* O157:H7 is, "product has not been tested for *E. coli* O157:H7."

B. What type of products can bear these labeling statements?

Establishments can only place these statements on product for use at other official establishments. When the Labeling and Consumer Protection Staff (LCPS) approves the use of instructional labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that ensure these products receive adequate lethality treatment. When LCPS approves the use of disclaimer labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plan. Establishments' use of these statements is entirely optional.

C. What verification activities should inspection program personnel conduct at establishments that place instructional or disclaimer statements

concerning *E. coli* O157:H7 on the labeling of raw ground beef products, raw ground beef components, or raw beef patty components?

1. When conducting an 04B04 procedure, inspection program personnel are to verify that the establishment has received sketch approval from LCPS and that it is maintained in the company's required labeling records (see 9 CFR 317.4(a)).

2. If inspection program personnel find that the establishment did not receive sketch approval or does not maintain that sketch approval in its official labeling records, they are to document the noncompliance on an NR under the Inspection System Procedure (ISP) code 04B04, and they are to document noncompliance with 9 CFR 317.4(a).

3. When performing a HACCP 01 or 02 procedure to verify the HACCP regulatory requirements are met for the production of such products, inspection program personnel are to verify that:

a. the instructional or disclaimer statement does not serve as a control or CCP to address *E. coli* O157:H7;

b. the establishment has not used the statement to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in the production of these products;

c. the use of any instructional statements is reflected in the establishment's decisionmaking documents (9 CFR 417.5) or hazard analysis (9 CFR 417.2(a)(1)); and

d. the establishment's HACCP plan for products on which it places a disclaimer statement includes a validated intervention for *E. coli* O157:H7.

4. If inspection program personnel find that the establishment's use of instructional statements does not meet the criteria in paragraph 3. a., b., or c. or that the establishment's use of disclaimer statements does not meet the criteria in paragraph 3. a. or b., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

5. If inspection program personnel find that the establishment's HACCP plan for product on which it places a disclaimer statement does not include an intervention for *E. coli* O157:H7, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV, using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. If inspection program personnel are concerned about

product moving outside the establishment, they should initiate a regulatory control action (9 CFR 500.2).

D. What verification activities should inspection program personnel conduct at establishments receiving raw ground beef components, raw beef patty components, or raw ground beef products with instructional or disclaimer statements concerning *E. coli* O157:H7?

1. When performing an 01 or 02 procedure to verify the HACCP requirements are met for products produced using such incoming products, inspection program personnel are to verify that establishments that receive such incoming products:

a. have addressed the use of incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with *E. coli* O157:H7; and

b. are following any instructional statements on the incoming products.

2. If inspection program personnel find that the establishment has not met the criteria in paragraph 1., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

3. Inspection program personnel should retain product produced using such incoming products under the following conditions:

a. the establishment is not following the instructional statement, or the establishment is receiving product bearing a disclaimer statement and its hazard analysis or decisionmaking documents do not address the use of the incoming product as if it were contaminated with *E. coli* O157:H7;

b. the establishment's process may not be adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels; and

c. the product is not intended for further processing that would destroy the pathogen.

4. If inspection program personnel retain product, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. Inspection program personnel should also notify the DO through supervisory channels of the conditions observed in association with the use of instructional or disclaimer statements. The DO may send an EIAO into the establishment to conduct a comprehensive food

safety assessment or invoke an enforcement action as described in 9 CFR 500.3 or 500.4.

PART X -- Retail Sampling

A. How is raw ground beef product sampling conducted at retail?

1. Retail sampling continues to be an important part of FSIS' *E. coli* O157:H7 sampling program. The likelihood that a specific retail facility will be sampled will depend on what the Agency learns about how raw ground beef product is handled at that facility.

2. When OPHS schedules samples to be taken at retail facilities, OPHS will send OPEER offices FSIS Form 10,210-3, "Requested Sample Programs." Specific information will be provided for the samples to be collected.

3. Program investigators are to make an effort to notify the retail facility the day before they plan to collect the raw ground beef product samples, so that the retail facility can prepare to hold the expected sampled lot. However, in cases when this is not possible, program investigators should try to get to the retail facility as close to the beginning of the grinding operation as possible.

4. Program investigators do not collect raw ground beef product that is received and sold as case-ready product or raw ground beef product that is only re-packaged at the retail store. Program investigators also do not collect raw ground beef product that is ground at retail if the retail facility only regrinds product previously ground at official establishments and does not conduct any practices that would introduce *E. coli* O157:H7 in the product (examples of situations in which samples should be taken include when the store mixes irradiated and un-irradiated beef; adds store trim; or grinds case-ready coarse ground product in a grinder also used to grind store trim if the sanitation program is not well documented, monitored, and verified for effectiveness).

5. When they collect the sample, program investigators obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of raw ground beef product sampled.

NOTE: When the source material for the sampled product is store-generated trim, the program investigator obtains and records the names and establishment numbers of the establishments that produced the product from which the store-generated trim was derived.

6. The supplier information is recorded on the retail worksheet that is used specifically for collection of raw ground beef products at retail.

7. In addition, the program investigator records the supplier lot number, production date, and other identifying information that would be useful to the supplier if it is later notified of a positive sample.

B. If a sample of raw ground beef product from a retail facility is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

The retail facility is notified of the positive *E. coli* O157:H7 result by the program investigator. FSIS will request a recall if any product in the sampled lot has been made available for retail sale. Program investigators and RMS are to work together to determine the necessity of product retention, detention, or recall. (See FSIS Directive 8080.1, Revision 3).

C. Whom does FSIS notify when a raw ground beef product sample at a retail facility is confirmed positive for *E. coli* O157:H7, and how is the notification given?

1. OPEER is notified of a retail positive through the Biological Information Transfer and E-mail System (BITES) and enters supplier information into the STEPS system.

2. The OPEER contact person accesses the STEPS system site with the list of suppliers for the sampled product that tested positive and follows the procedures for notifying suppliers in Part III. B.

D. If FSIS finds raw ground beef product produced at retail positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling at the retail facility?

After an FSIS sample tests positive, program investigators should contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up sample. The request must include the retail facility name and address, the number of forms (in this case, 1), the type of sample to be collected (i.e., product sample), the purpose of the request (i.e., follow-up sampling in response to a confirmed *E. coli* O157:H7 positive in raw ground beef), the sample form number of the original positive sample triggering this request, the date by which the form is needed, and the program investigator's name and work address. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, "Requested Sample Programs" or in revisions to FSIS Directive 10,210.1, under the appropriate project. In addition, when feasible, FSIS will schedule

verification activities, including testing, at the supplying establishment following an FSIS positive sample from a retail facility.

PART XI -- Import Sampling

A. How is raw ground beef product sampling conducted at import establishments?

1. OPHS works with the Office of International Affairs (OIA) to send import inspection personnel FSIS Form 10,210-3, "Requested Sample Programs." Certain information will be provided specific to the sample to be collected. Import inspection personnel are to follow the corresponding instructions found in the Import Manual of Procedures (Part 3, Section 5). When OPHS begins sending the form electronically, the Automated Import Information System (AIIS) will schedule samples and send the form electronically to import inspection personnel.

2. Import inspection personnel notify the import establishment management of the reason a sample is being collected for *E. coli* O157:H7 testing (routine FSIS verification testing, increased sampling, or intensified sampling). Imported products may be under increased sampling if OIA has determined that product may be at risk of being contaminated with *E. coli* O157:H7. When a shipment is to be sampled for FSIS testing, the importer, broker or applicant has an opportunity to voluntarily hold the product until the results are reported. Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. When a foreign establishment is under intensified sampling for *E. coli* O157:H7, FSIS holds the product to be sampled until negative results are reported by the laboratory.

B. If a sample of imported raw ground beef product collected from an import establishment is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

1. If the product is on hold at the import establishment, whether on FSIS hold or voluntary hold, import inspection personnel will initiate refused entry procedures on the entire lot.

2. FSIS will request a recall if any product in the sampled lot has been released into commerce. Program personnel, including OIA, the DO, and RMS, work together to determine the necessity of product retention, detention, or recall. OIA will coordinate with the DO to provide information to inspection program personnel and program investigators as necessary.

C. Whom does FSIS notify when an imported raw ground beef product collected at an import establishment is confirmed positive for *E. coli* O157:H7, and how is notification given?

1. If the lot has not moved into commerce, import inspection personnel notify establishment management, which is responsible for notifying the importer of record. Import inspection personnel should refer to Part 4, Section 11 of the Import Manual of Procedures for guidance on refused entry procedures.

2. If the lot has moved into commerce from the import establishment:

a. the import inspection personnel should send a copy of FSIS Form 9540-1 and the foreign health certificate via facsimile to OIA/Import Inspection Division.

b. OIA notifies the head of the inspection service in the country of origin of the sample that has been confirmed positive for *E. coli* O157:H7 and requests that appropriate action be taken.

D. If FSIS finds raw ground beef product collected at an import inspection establishment positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling of product from the foreign establishment?

Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. An intensified level of sampling is automatically generated by the AIIS for the next 15 consecutive shipments of product from the foreign establishment presented at port-of-entry anywhere in the United States. Under an intensified level of sampling, the shipment is placed on FSIS hold when the sample is collected, until results are reported. Import inspection personnel should follow the procedures outlined in the Import Manual of Procedures (Part 3, Section 5) for guidance.

All questions related to this directive should be directed through normal supervisory channels.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy and Program Development

Attachment 1

Questions and Answers

1. Will FSIS sample trimmings and other ground beef and beef patty components?

FSIS may sample and test beef manufacturing trimmings and other raw ground beef and beef patty components at a supplying establishment when that establishment has supplied product to grinders that tested positive for *E. coli* O157:H7 after it was ground. In the future, FSIS intends to develop a random sampling and testing program for raw ground beef components and beef patty components and non-intact beef products other than ground beef, such as mechanically tenderized and injected steaks and roasts.

2. Will an establishment that has incorporated testing of trimmings and ground beef products for *E. coli* O157:H7 into its HACCP plan as a verification procedure be exempt from FSIS sampling and testing?

No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. However, FSIS' verification testing will become more risk-based. Establishments that have designed and implemented sampling and verification testing, with a high degree of confidence of finding the pathogen in both trim and finished ground product, presumably present a lower risk for producing adulterated product than one that conducts this activity only on trim or only on finished ground product and, therefore, will be sampled less frequently than other establishments.

3. What factors will be considered by FSIS in establishing risk-based verification testing for *E. coli* O157:H7 in federally-inspected establishments?

FSIS will weight its sample scheduling process so that an establishment producing a large volume of raw ground beef products will be sampled more frequently than an establishment with a lower volume of production of raw ground beef products. In addition, FSIS will also consider seasonality of *E. coli* O157:H7 prevalence and other factors, such as the number of suppliers, in developing a sampling plan based on risk. FSIS will also sample ground beef product at inspected establishments that form ground beef patties but do not grind the product. However, FSIS will also sample ground beef product at these establishments less frequently than at a plant that grinds product.

4. What factors are considered by FSIS in ensuring that retail sampling focuses on the highest risk product?

Retail sampling focuses on higher risk products by focusing on product that either includes store-generated trim or was ground using equipment that had been used to grind store-generated trim without being adequately cleaned.

5. Can an establishment have a CCP for product disposition based on finished product testing?

If a grinder has internal controls for *E. coli* O157:H7 and receives product from suppliers (both slaughter and fabrication establishments) that have controls for *E. coli* O157:H7, and the grinder and its suppliers conduct rigorous verification testing at multiple points during the production process, a CCP for disposition based on finished product testing for *E. coli* O157:H7 may be appropriate. A CCP for disposition based on finished product *E. coli* O157:H7 testing should employ testing at a level sufficient to find the organism if present at very low frequency. Corrective and preventive action in response to a positive in finished product testing should accompany an examination of the whole system, not merely disposition of the product.

6. Can the FSIS guidance materials suffice for supporting documentation for validation of CCPs, or does FSIS expect the scientific supporting documents to be more specific than a copy of the FSIS guidance materials?

The guidance materials that FSIS has developed for slaughter establishments, grinders, and suppliers on minimizing the risk of *E. coli* O157:H7 contamination included the parameters of certain studies. If establishments can demonstrate that their process meets the parameters of those studies, the FSIS guidance materials would be sufficient documentation of their validation. However, if the process parameters in the establishment differ from those in the FSIS guidance materials, in-house validation would be necessary.

7. If the establishment or FSIS tests raw ground beef products, raw ground beef components, or raw beef patty components for *E. coli* O157:H7 and finds more than one positive, do these findings signify a HACCP failure?

The establishments' or FSIS' finding more than one positive would not alone be a HACCP failure. However, FSIS would expect the establishment to identify *E. coli* O157:H7 as a hazard reasonably likely to occur (if it has not already done so). In addition, the establishment should attempt to determine the cause of the positive findings and would likely need to examine its intervention methods to determine why they are not working. Some establishments have adopted intensive raw material and finished product testing and supplier controls within their Sanitation SOPs and HACCP systems. In these situations, inspection program personnel should verify that the establishments control procedures to determine whether a HACCP failure is occurring. In other situations, the establishment may decide to

conduct carcass mapping to identify areas of carcass contamination (if the establishment conducts slaughter or fabrication). In addition, if FSIS testing finds *E. coli* O157:H7, the establishment may decide to intensify its verification program or may decide to ensure that the sensitivity of its testing method is equivalent to FSIS' testing method.

8. Can an inspector collect and submit a ground beef sample prior to pre-shipment review being performed by the establishment?

Inspection program personnel should become familiar with the production process and provide notification to the establishment that a sample will be collected in time for the establishment to hold the sampled product. Some establishments have an extensive verification testing program, sample every "lot" of ground beef product produced, and have a CCP for product disposition. In this scenario, the establishment cannot conduct pre-shipment review until the result from the sample has been received. If the establishment has no interventions in place after the product is sampled that address the presence of the pathogen of concern, the establishment could conduct a pre-shipment review on this product up to this point with a note indicating that the product is being held pending laboratory analysis. Inspection program personnel could verify that the establishment meets the corrective action requirements of 9 CFR 417.3, if a positive result is received by the establishment. If disposition of product is delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product. When the results for both samples (FSIS sample and the establishment sample) have been received, the establishment could then conduct a "final" pre-shipment review. In a scenario similar to this, inspection program personnel could submit the sample prior to the final pre-shipment review being conducted.

9. If an establishment makes case-ready product and requests that the inspector give it notice the day before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, should the inspector accommodate the request?

Yes. The purpose of FSIS sampling is to provide verification that the establishment's process is producing product that is not adulterated by *E. coli* O157:H7. It is not to compromise the establishment's ability to fill its orders.

10. What is the purpose of follow-up sampling by FSIS after FSIS finds that a sample of product is positive for *E. coli* O157:H7?

FSIS generally always will collect at least one supplemental verification sample of product immediately following corrective actions by the establishment when FSIS finds a sample of product from an official establishment positive for *E. coli* O157:H7. This follow-up verification sample is expected to be larger (e.g.,

double the size of the regular verification sample), and FSIS expects to double the number of sub-samples that it analyzes. The results will be reported as either positive or negative, like other routine verification sample results. FSIS' follow-up sampling is one of several activities FSIS conducts to verify the adequacy of the establishments' corrective actions following an FSIS positive *E. coli* O157:H7 finding.

11. Is FSIS notified of *E. coli* O157:H7 positive Agriculture Marketing Service (AMS) results? If so, what actions do inspection program personnel take in response to such notification?

Yes, FSIS is notified of *E. coli* O157:H7 positive AMS results. AMS reports potential positives and confirmed positives to FSIS. When the DO is notified of an AMS potential positive, FSIS reacts as if the product were found presumptive positive by FSIS (see Part III, A.). If the product is confirmed positive by AMS, the establishment needs to ensure its proper disposition and to conduct appropriate corrective actions. An AMS result is an official government result.

12. Why must establishments obtain sketch approval from FSIS to use labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components?

The labeling of ground beef products, single-ingredient raw ground beef components, or single-ingredient raw beef patty components that includes special instructions or disclaimer statements concerning *E. coli* O157:H7 cannot be generically approved because FSIS considers these special instructions or disclaimers to be special claims (see 9 CFR 317.5(b)(2)).

13. If FSIS finds that establishments have been using labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components without sketch approval from FSIS, will FSIS request that the establishments recall the product?

No. FSIS will not request that establishments recall product that has already been shipped with unapproved labels because use of such product will not result in adverse health consequences. However, FSIS will rescind such labels, and the establishment would need to submit them to FSIS for sketch approval.

14. Can instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7?

Labeling is not a means to prevent, eliminate, or reduce pathogens. Therefore, instructional or disclaimer statements cannot be used as CCPs or interventions for *E. coli* O157:H7. If the establishment has determined that *E. coli* O157:H7 is

a hazard reasonably likely to occur in its production of raw ground beef products, raw ground beef components, or raw beef patty components, the establishment must have an intervention to address the hazard.

15. Can establishments use instructional or disclaimer labeling statements to justify a determination that *E. coli* O157:H7 is not a hazard reasonably likely to occur in their production of beef products?

No. Because labeling is not a means to control pathogens, establishments may not use these labels to justify their determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in their production of these products.

16. Can product labeled "for cooking only" go to an establishment that cooks product intended for additional further processing?

Yes. Even if the product will undergo further processing after it leaves the cooking establishment, as long as the cooking establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

17. How should the placement of instructional statements be reflected in HACCP plan documents?

The placement of any instructional statement addressing *E. coli* O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty components must be reflected in an establishment's decisionmaking documents and hazard analysis.

For example, if an establishment is placing the statement "for cooking only" or "for full lethality treatment" on raw ground beef products, raw ground beef components, or raw beef patty components, the establishment's hazard analysis should show how the establishment is ensuring that the product will go for cooking only or for other full lethality treatment only. If the establishment places a "for cooking only" statement on the product and cooks the product in the establishment, the establishment's flow chart should show the cooking steps the product will undergo. If the establishment places a "for cooking only" statement on the product and ships it to outside establishments, the shipping establishment should have controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that is not intended for cooking, it should have controls in place to segregate product intended for cooking from product not intended for cooking. If an establishment places the statement "for cooking only" on its finished product, but the establishment has not addressed the intended use of its finished product in its decisionmaking documents or hazard analysis, the establishment's hazard analysis and decisionmaking documents would not be consistent with the

information contained in the instructional statement, and the establishment would not be in compliance with 9 CFR 417.5.

18. Why are establishments that place labels on raw beef products that include a disclaimer statement concerning *E. coli* O157:H7 required to have an intervention for the pathogen in their HACCP plan?

An establishment may use a disclaimer statement, such as, "not tested for *E. coli* O157:H7," on labels of raw ground beef products, raw ground beef components, or raw beef patty components only if it has an intervention for the pathogen in its HACCP plan for these products. A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (9 CFR 417.6).

19. How are inspection personnel to document noncompliances involving labeling and disclaimer statements?

Inspection program personnel are usually to cite 9 CFR 417.5 and to use the recordkeeping trend indicator when documenting on an NR most of the possible noncompliances involving labeling and disclaimer statements. Under 9 CFR 417.5, required records documenting the establishment's HACCP plan include: a written hazard analysis, supporting documentation of the hazard analysis, a written HACCP plan, and decisionmaking documents associated with selection and development of CCPs and critical limits.

a. If the establishment's use of instructional statements concerning *E. coli* O157:H7 is not reflected in its decisionmaking documents or hazard analysis, the establishment is not in compliance with 9 CFR 417.5, because its records do not show that the establishment has considered its use of these instructional statements in its hazard analysis or HACCP plan.

b. If the instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7, the establishment is not in compliance with 9 CFR 417.5 because the establishment's decisionmaking documents or hazard analysis cannot support its use of instructional or disclaimer statements as controls or CCPs.

c. If the establishment has used instructional or disclaimer statements to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur, the establishment is not in compliance with 9 CFR 417.5 because the establishment's decisionmaking documents or hazard analysis incorrectly

concluded that labeling statements would prevent *E. coli* O157:H7 from becoming a hazard reasonably likely to occur in the establishment.

d. If an establishment receiving product with instructional or disclaimer statements has not addressed the use of such products in its decisionmaking documents or hazard analysis, or does not have data to validate that these products will receive adequate lethality treatment, the establishment is not in compliance with 9 CFR 417.5 because its records do not show that the establishment has adequately addressed the use of these incoming products in the hazard analysis for those products in which such incoming products will be used.

Attachment 2

PROCEDURES FOR SAMPLING RAW GROUND BEEF COMPONENTS AND RAW BEEF PATTY COMPONENTS:

Refer to the page in FSIS Directive 10,210.1 that corresponds to the project code in Block 14 of FSIS Form 10,210-3, Requested Sample Programs, for further collection instructions.

Sample Size:
The FSIS laboratory requires approximately 1.5 pounds (24 ounces or 680 grams) but no less than 1.25 pounds (20 ounces or 570 grams) of product.

Sample Chilling:
If the sample is warmer than 40°F/4.4°C when the sample is taken, place it in a cooler to chill it before shipping.
Prior to shipping the sample, pre-chill the shipping container in a refrigerated cooler that is between 28°F and 45°F for at least 8 hours.

Randomized or Representative Sampling:
As best as practical, select a representative sample by one of the two following procedures:

1. **Time**: Throughout the production lot, as defined by the establishment, as boxes or combo bins are filled, collect samples at random times. Use standard procedures for identifying "random times".
   If random times are not practical use the "Space" option below.

2. **Space**: At or toward the end of the production lot, as defined by the establishment, note the number of boxes or combo bins containing the requested product types. Take the square root of that number and round up to the next whole number (i.e., if the number of boxes is 29, the square root is 5.38; the next whole number is 6). That number, or no more than 10, is the number of containers to be sampled.
   Use a standard random number procedure to select which containers to sample. Select representative samples from the top of the filled boxes or combo bins. These pieces should have collected representative bacteria from the product contact surfaces during the course of production.

Sampling Procedure:
There will be three basic sampling procedures based on size of sample pieces:

1. Very small pieces less than the size of an ordinary thumb, such as AMR, or LBT/LFTB.
   For very small pieces, use the laboratory-supplied scoop or spoon to collect the sample.

2. Small pieces less than the size of an ordinary palm, such as head meat or trimming.
   For small pieces, use the laboratory-supplied scoop, tongs, or hook to collect the sample.

3. Chunks and pieces larger than an ordinary palm, such as chucks and plates: Call for help from an establishment employee with an establishment knife and laboratory-supplied hook. Have the employee sanitize knife and hook in the same manner as is done on the boning/trim line. From each of the designated containers (or during the day) "Grab sample" pieces with the hook. From each piece, slice a thumb to palm-sized piece of surface, no thicker than ½ inch (or 1 cm). Place the samples into the sterile sample bag, using the hook or laboratory-supplied tongs.